

REMARKS**I. Status Of The Claims.**

Claims 1-26 are pending in the application. Claim 25 is rejected under 35 U.S.C. § 112. Claims 1, 4-9, 10-13, 17-18, 22-24, and 26 are rejected under 35 U.S.C. § 102(e), and Claims 2-3, 14-16, and 19-21 are rejected under 35 U.S.C. § 103(a). This Response and Amendment adds new Claim 27 and cancels Claims 25 and 26.

II. Amendments to the Claims.

This Response and Amendment adds new Claim 27. Support for Claim 27 is found on page 8, lines 11-13. Also, Figure 3 shows an interface between serum 215 or plasma and air 213. As described on page 4, lines 19-30, and shown in Figure 3, the second, *e.g.*, infrared, light beam is transparent to the material and the air, but is absorbed by serum 215. Thus, the interface between the air 213 and the serum 215 can be sensed as the second light beam is transmitted through the air and the container, made up of the material to give an infrared light reading 223. The first, *e.g.*, visible, light beam is transparent to the material, the air, and serum and the first light beam is detected as it is transmitted through the serum, air, and the container, made up of the material to give a visible light reading 239. In this manner, the interface between plasma or serum and the air is determined. Accordingly, new Claim 27 does not add new matter.

III. Amendments to the Specification.

The Specification has been amended in the paragraph beginning on page 7, line 18 and ending on page 7, line 24 to renumber the cap, initially labeled as 239, to 240. This amendment corrects a minor typographical error and does not add new matter. Entry of these amendments is respectfully requested.

IV. The Drawings.**A. Amendments to the Drawings.**

Substitute Figures 1-6 are submitted with this Response. Figures 2 and 3 have been revised to renumber the cap, initially labeled as 239, to 240. Figures 4 and 5 have also been revised to remove an extraneous smiley face shown on the tube. Acceptance of these drawings is respectfully requested.

B. The Objection To the Drawings.

The drawings are objected to for the reasons indicated on page 2 of the Office Action dated April 11, 2003 (the "Office Action"). In response, Claim 25 is canceled and Figures 2 and 3 have been revised to renumber the cap as described above. Applicants believe these revisions obviate the objection. Withdrawal of the objection is respectfully requested.

V. The Rejection Under 35 U.S.C. § 112.

Claim 25 has been rejected under 35 U.S.C. § 112, paragraph 2 for the reasons stated in numbered paragraph 3 of the Office Action dated April 11, 2003. This Response and Amendment cancels Claims 25. Withdrawal of the objection is respectfully requested.

VI. Applicants Invention.

The essence of Applicants invention is the use of multiple light sources at varying wavelengths for identifying interfaces in a sample container. A first light source, which is substantially blocked by cells, but transmitted by serum and plasma is projected onto a container. A second light source, which is blocked by serum, plasma, and cells, is also projected onto the container. A portion of the unblocked light sources that is transmitted through each container is then detected and the detected light reading is used to determine the interfaces in a container. The interfaces, different light sources, and light readings are illustrated in Figures 2 and 3.

VII. The 35 U.S.C. § 102(e) Rejection.**A. The Rejection Over Cadell et al. (US 6,195,158 B1).**

Claims 1, 4-8, 10-13, 17-18, 22-24, and 26 are rejected under 35 U.S.C. § 102(e), as anticipated by Cadell et al. (US 6,195,158 B1) for the reasons stated in numbered paragraph 7 of the Office Action. Applicants respectfully submit that Cadell et al does not describe all of the limitations of the claimed invention and request reconsideration of this rejection based on the following comments.

Independent Claims 1, 12, 18, 22, and 23 are each limited to projecting onto a container first and second light beams, as shown in Figure 3. As contained in limitations a) and b) of each of Claims 1, 12, 18, 22, and 23, the first light beam is substantially transmitted by serum, plasma, and a material, and through the container, but is substantially blocked by

cells. The second light beam is substantially blocked by serum, plasma, and cells, but is substantially transmitted by the material and through the container. The portions of the first and second light beams that are transmitted through the container are then detected and an interface between a layer is determined.

It is Applicants position that Cadell et al. does not describe two different light beams that meet the above described limitations a) and b) contained in Claims 1, 12, 18, 22, and 23. Cadell et al. describes using LEDs 16 to calculate fluid volume from the measured tube diameter and the measured height of fluid above the gel barrier. (*See, e.g.*, Cadell et al. col. 2, lines 24- 65; col. 3, line 66 through col. 4, line 31). The Office has not pointed to a portion of Cadell et al. that describes projecting multiple light beams that are transmitted or substantially blocked by differing layers in a container as claimed by Applicants, and it is Applicants position that this claimed feature of the invention is in fact not taught or suggested by Cadell et al. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of independent Claims 1, 12, 18, 22, and 23, and their dependent Claims 2-11, 13-17, 19-21, and 24 on this basis.

B. The Rejection Over Kawano (US 2002/0067476 A1).

Claims 1 and 9 are rejected under 35 U.S.C. § 102(e), as anticipated by Kawano (US 2002/0067476) for the reasons stated in numbered paragraph 8 of the Office Action.

Applicants respectfully submit that Kawano et al does not describe all of the limitations of the claimed invention and respectfully request reconsideration of this rejection based on the following comments.

Independent Claim 1 is directed to a method for detecting the location of at least one interface in a container . . . having at least one layer of serum, plasma, and cells. Claim 1 is limited to first and second light beams that are projected onto a container, where the first and second light beams are limited to:

- a) “a first detecting light beam that is substantially transmitted by serum, plasma, and a material, but is substantially blocked by cells, . . . ;” and
- b) “a second detecting light beam that is substantially blocked by serum, plasma, and cells, but is substantially transmitted by the material, . . . ;”

Independent Claim 1 is also limited to element e) "determining the location of at least one interface from the detected portions."

It is Applicants position that Kawano does not describe two different light beams that meet limitations a) and b) as shown above; and element e), determining the location of an interface.

1. Kawano does not describe element e) of Claim 1, "determining the location of at least one interface".

Kawano describes an analytical method and apparatus for carrying out an analysis of the components of a blood sample, which is a whole blood sample and not separated into interfaces. (See, e.g., Kawano page 1, par. 2-8.) Kawano teaches that blood that has been separated into blood plasma and red blood cells (*i.e.*, separated into layers with an interface) is a problem and that it is the object of the invention to carry out an analysis of the object characteristics of blood (*i.e.*, "the chemical components and physicochemical characteristics . . . of blood such as red blood cells, hematocrit, hemoglobin, total protein, total cholesterol and blood sugar"). (See, e.g., Kawano, page 1, par. 2-9; and page 3, describing the procedure for analyzing the object characteristics of the blood sample

2. Kawano does not describe elements a) and b) of Claim 1.

Kawano describes using near infrared (NIR) spectroscopy to analyze the object characteristics of the blood. The Office has not pointed to a portion of Kawano that describes multiple light beams that are transmitted or substantially blocked by differing layers in a container as claimed by Applicants in elements a) and b) of Claim 1.

It is Applicants position that elements a), b), and e) of Claim 1 are not described by Kawano. Further, these elements are not taught or suggested by Kawano. Applicants respectfully request reconsideration and withdrawal of the rejection of independent Claim 1 and dependent Claim 9 on this basis.

VIII. The 35 U.S.C. § 103(a) Rejection.

A. The Invention Is Non-obvious Over Cadell et al.

Claims 2-3, 14-16, and 19-21 are rejected under 35 U.S.C. § 103(a) as unpatentable over Cadell et al. for the reasons stated in numbered paragraph 10 of the Office Action.

Applicants respectfully request reconsideration of the § 103(a) rejection based on the following comments.

As described in Section VII (A), *infra*, Cadell et al. does not describe all of the claimed limitations of independent Claims 1, 12, 18, 22, and 23. Further, Cadell et al. does not provide a suggestion or motivation to modify the reference to project multiple light beams that are transmitted or substantially blocked by differing layers in a container as claimed by Applicants. It is Applicants position that a *prima facie* case of obviousness for independent Claims 1, 12, 18, 22, and 23 and dependent Claims 2-3, 14-16, 19-21, and 24 has not been established. Applicants submit that all claims are patentable over Cadell et al. and respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

B. The Invention Is Non-obvious Over Kawano.

The Office has not rejected the Claims under 35 U.S.C. § 103(a) over Kawano. However, in the interest of completeness, Applicants submit that all claims are patentable over Kawano under 35 U.S.C. § 103(a).

As described in Section VII (B), *infra*, Kawano does not describe all of the claimed limitations of independent Claims 1, 12, 18, 22, and 23. Kawano describes the use of 1 light source only and does not provide a suggestion or motivation to modify the reference to project multiple light beams that are transmitted or substantially blocked by differing layers in a container as claimed by Applicants. Further, Kawano does not provide a suggestion or motivation to modify the reference to determine the location of an interface, as claimed by Applicants. It is Applicants position that Kawano teaches away from Applicants claimed invention by describing the method for separating the blood into blood plasma and red blood cells (*i.e.*, layers having an interface) as “problematic” and provides a method and apparatus to analyze blood without separating the various components. Thus, Kawano does not support a *prima facie* case of obviousness for independent Claims 1, 12, 18, 22, and 23 and their dependent Claims.

Based on the forgoing comments, withdrawal of the rejection of under 35 U.S.C. § 103(a) and allowance of all Claims is respectfully requested.

CONCLUSION

Applicants believe that all pending claims are in condition for allowance and such action is earnestly requested. If the present amendments and remarks do not place the Application in condition for allowance, the Examiner is encouraged to contact the undersigned directly if there are any issues that can be resolved by telephone with the Applicants' representative.

The Commissioner is authorized to charge \$410 for an extension for response within a second month. No other fees are believed due by this Response. If, however, any other fees are due, the Commissioner is authorized to charge any other fees or credit any overpayment associated with this Response and Amendment to Deposit Account No. 19-2090.

Respectfully Submitted,
SHELDON & MAK PC

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